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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Daniel Baumgartner

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EXAMINER

YANG, ANDREW

ART UNIT

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3733

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,495	Applicant(s) BAUMGARTNER ET AL.	
	Examiner ANDREW YANG	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-22 and 24-50 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47-50 is/are allowed.
- 6) ☒ Claim(s) 1,2,4-22,24,25,27,28 and 31-46 is/are rejected.
- 7) ☒ Claim(s) 26,29 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to Applicants' amendment filed on February 19, 2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6, 7, 8, 11, 13, 19, 28, 34, and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stubstad et al. (U.S. Patent No. 3867728). Stubstad et al. discloses a prosthesis for spinal repair having a central axis, a bottom member 12, a top member 11, a central part 15, and a sheathing system. The top member 11 is considered to have a closing plate 18 of metal or rigid plastic (Column 8, Lines 1-2) with a layer 19 for contacting an adjacent vertebra and a cover plate 17 in contact with the closing plate 18. The bottom member 12 is configured in the same way. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the closing plates out of titanium, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

The sheath 13 is made of a plurality of layers 14 of silicone elastomer that is passed through by a mesh of filaments or what is considered to be the fiber system that is entirely imbedded in the sheathing body 13. The fiber system is a Darcon mesh and is considered to be a woven material. The top and bottom plates 11, 12 also have fiber systems 21, 21' that span across the cover plates and are mechanically mounted to the plates by filament 24. Since the fiber system is entirely mounted in the sheath it cannot move relative to the sheath. The sheathing body is made of a silicone elastomer (Column 7, Lines 40-45). The implant has a central axis extending from top plate 11 to bottom plate 12 and the fiber system 21, 21' is multilayered along the axis (Column 8, Lines 5-30). Stubstad et al. does not disclose fiber system of the top and bottom cover plates and the fiber system in the sheathing body to be a single entity. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the fiber system of Stubstad et al. as a single entity, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Claim 35, 36, 37, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casutt (U.S. Patent No. 6645248) in view of Eldridge et al. (U.S. Patent No. 6120539).

Casutt discloses an intervertebral implant with a top plate 1, a bottom plate 2, and a central part 4. The top and bottom plates 1, 2 each have an internal surface and an external surface for contacting first and second vertebrae. The central part 4 has a

core 3, and a fiber system 5 located between the internal surfaces of the top and bottom plates (Figure 1). The fiber system 5, is connected to the top and bottom plates 1, 2 and surrounds the core. The fiber system has a plurality of interwoven fibers (Column 5, Lines 40-45). The fiber system has a cylindrical shape (Figure 1). With regard to claim 37, it would have been obvious to one having ordinary skill in the art at the time the invention was made construct the fiber system of Casutt out of UHMWPE, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Casutt fails to disclose an elastic sheathing body that at least partially surrounds the fiber system. Eldridge et al. teaches surrounding a mesh structure with an elastic sheathing body 16 at least partially in order to prevent unwanted tissue ingrowth (Column 3, Lines 65-67). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Casutt with a fiber system surrounded at least partially by an elastic sheathing body in view of Eldridge et al. in order to prevent tissue adhesion. It is noted that such a modification would also provide for the elastic sheathing body to be attached to the top and bottom plates.

Claims 1, 4, 5, 9, 10-12, 14-22, 24, 25, 27, 31-35, 38, 43-46 rejected under 35 U.S.C. 103(a) as being unpatentable over Casutt (U.S. Patent No. 6645248) in view of Eldridge et al. (U.S. Patent No. 6120539) and further in view of Amin et al. (U.S. Publication No. 2004/0241238).

Casutt discloses an intervertebral implant with top and bottom plates 1, 2, a central part 4 and a fiber system 5. The fiber system 5 is joined to the cover plates 1, 2 and guided over an external surface of both cover plates 1, 2 so that the fiber system 5 at least partially surround the central part 4 as well as both cover plates 1, 2 (Figure 7). The central part 4 has a cavity that is filled with an incompressible medium such as a liquid (Column 5, Lines 5-20) and is surrounded by the fiber system, which can be considered an elastic formed body. The fiber system is adhered to the cover plates in a form locking manner in a groove 9 with a ring 11. The top and bottom cover plates 1, 2 each have a groove, and therefore the top and bottom cover plates having a plurality of grooves/channels/openings (Figures 6-12).

The fiber system 5 can be one endless fiber (Column 5, Lines 55-56) and can be single layered (Column 5, Lines 36-37). The fiber system is braided, woven, or knitted (Column 5, Lines 35-40) and is therefore considered to have at least first and second fibers interwoven with each fiber defining an angle with the central axis of the implant. The range of 15-60 degrees for each angle would have been obvious to one having ordinary skill in the art at the time the invention was made, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the

optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Casutt fails to disclose a sheathing body wherein that surrounds the fiber system. Eldridge et al. teaches a fiber system 12, 14 and a sheath 16. The sheath 16 is fused with a first layer 14 of the fiber system. The sheath 16 is attached to and at least partially surrounds the fiber system in order to discourage tissue ingrowth (Column 3, Lines 65-67). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Casutt with a fiber system at least partially surrounded in a sheath in view of Eldridge et al in order to discourage tissue ingrowth. Furthermore, the device of Casutt in view of Eldridge et al. would have a fiber system that can move relative to the sheathing since only one layer is fused to the sheath.

With regard to claim 4 With regard to claims 2 and 3, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the series of parallel teeth of the device of Casutt as modified by Eldridge et al. with the fiber system having a thickness and the sheath having a thickness wherein the thickness of the fiber system divided by the thickness of the sheath and times 100 is 80%-350%, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With regard to claim 20, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the device of

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Casutt as modified by Eldridge et al. with a cavity in the shape of a hollow cylindrical, hollow prismatic, ellipsoid, a partial sphere, or a barrel shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing a forming edge in the heating portion or clamp. In re Dailey and Eilers, 149 USPQ 47 (1966).

With regard to claim 31, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Casutt as modified by Eldridge et al. with fibers made from UHMWPE, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

With regard to claim 33, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the series of parallel teeth of the device of Casutt as modified by Eldridge et al. with the fiber system a diameter in a range of .005mm to .025mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Casutt and Eldridge et al. fail to disclose the device have a top and bottom closing plate. Arnin et al. teaches a spinal disc prosthesis having an inner implant 20 with a top cover plate 22, a lower cover plate 24. A central part has a core 26 and a sheathing body 32 attached to the upper and lower cover plates 22, 24. Each of the

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upper and lower cover plates 22, 24 is inserted into an outer implant portion comprising a top closing plate 14 and a lower closing plate 16 each having an anchoring element 18. The configuration allows for easy replacement of the spinal unit without using any intricate procedures (Paragraph 17). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Cassutt as modified by Eldridge et al. with top and bottom closing plates further in view of Arnin et al. so that the spinal unit can be replaced without any intricate procedures. It is noted that the combination of Cassutt and Eldridge et al. would have the elastic sheathing body attached to the top and bottom cover plates.

Allowable Subject Matter

Claims 26, 29, and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 47-50 are allowed.

Response to Arguments

In response to Applicants' argument that Stubstad fails to disclose top and bottom closing plates, the arguments have been addressed in the body of the rejection. The top member 11 is considered to have a closing plate 18 of metal or rigid plastic (Column 8, Lines 1-2) with a layer 19 for contacting an adjacent vertebra and a cover plate 17 in contact with the closing plate 18. The bottom member 12 is configured in the

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same way. Furthermore, it is still considered that the plurality of silicone members 14 wrapped around the core of Stubstad is an elastic sheath that is embedded with a fiber system.

Applicant's arguments with respect to claims 34, 35 and all depending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW YANG whose telephone number is (571)272-3472. The examiner can normally be reached on IFP.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew Yang/
Examiner, Art Unit 3733
5/7/2008

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733